

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division**

EXELA PHARMA SCIENCES, LLC;
EXELA PHARMSCI, INC; and
EXELA HOLDINGS, INC.

Plaintiffs,

vs.

HON. DAVID J. KAPPOS,
Under Secretary of Commerce for Intellectual
Property and Director of the United States
Patent and Trademark Office; and

UNITED STATES PATENT AND
TRADEMARK OFFICE

Defendants.

Civil Action No. 1: :12-cv-00469
(LO/JFA)

OPPOSITION TO DEFENDANTS MOTION TO DISMISS

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I. INTRODUCTION

The present action concerns the U.S. Patent and Trademark Office's ("PTO") improper revival and issuance of U.S. Patent No. 6,992,218 ("the '218 patent"). Pertinent facts are as follows. On June 6, 2000, SCR Pharmatop, a French entity, filed French patent application FR 00 07231. A year later, SCR Pharmatop filed PCT/FR01/01749 in the United States claiming priority to FR 00 07231. Based upon 35 U.S.C. § 371, the applicant needed to submit certain information to PTO by December 6, 2002. SCR Pharmatop did not meet this deadline. As such, PCT/FR01/01749 was abandoned under the express terms of 35 U.S.C. § 371(d), which states that "[f]ailure to comply with these requirements shall be regarded as abandonment of the application by the parties thereof, **unless it be shown to the satisfaction of the Director that such failure to comply was unavoidable.**" (emphasis added)

Once abandoned, any invention disclosed in PCT/FR01/01749 passed into the public domain and became free for all to exploit in the United States. *Pennock v. Dialogue*, 27 U.S. 1, 16 (1829); *see also* 37 C.F.R. § 1.495 ("An international application becomes abandoned as to the United States thirty months from the priority date if the requirements of paragraph (b) of this section have not been complied with within thirty months from the priority date.").

On or about December 23, 2002, the assignee of the '218 patent, SCR Pharmatop, entered into a license agreement with Bristol-Myers Squibb (BMS). Section 5.1 of that license agreement (Ex. 1) required that SCR Pharmatop "use its best efforts to diligently prosecute" certain patent applications, including PCT/FR01/01749 as defined in section 1.16. However, when SCR Pharmatop signed this agreement, PCT/FR01/01749 was already abandoned. Thus, on or about January 2, 2003, SCR Pharmatop petitioned to revive PCT/FR01/01749, declaring only that its delay in meeting the national stage requirements was "unintentional," rather than "unavoidable" as required by 35 U.S.C. § 371(d). On April 23, 2003, PTO granted the petition

under 37 C.F.R. § 1.137(b), which governs “unintentional” delays. In granting the petition, PTO rejected the “unavoidable” standard chosen by Congress in § 371(d). However, PTO has no authority to add rights not granted by Congress. *Merck & Co. v. Kessler*, 80 F. 3d 1543, 1550 (Fed. Cir. 1996) (“Congress has not vested the Commissioner with any general substantive rulemaking power . . .”). Even if PTO had such authority, it cannot reject the statutory scheme chosen by Congress for revival of national stage patent applications.¹ At least one court has already found PTO’s rejection of § 371(d) unlawful.²

Realizing weakness in its position on the merits, PTO seeks victory on procedural grounds. PTO takes the “throw everything at the wall and see what sticks” approach. Nonetheless, PTO’s motion to dismiss should be rejected for at least the following reasons.

First, PTO’s rejection of the “unavoidable” standard in § 371(d) is reviewable. Agency action is presumptively reviewable unless clear and convincing evidence counsels otherwise. Rather than counseling against the strong presumption of reviewability, legislative history of both the Administrative Procedure Act (“APA”) and 1952 Patent Act show clear Congressional intent for review of PTO decisions. Indeed, following passage of the APA, the then Commissioner of Patents understood that, following passage of the APA “the courts will welcome the appellant as exercising a right of review and not merely treat him as a suppliant for extraordinary remedy.”

¹ *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-843 (1984) (“If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.”); *White v. United States*, 543 F.3d 1330, 1338 (Fed. Cir. 2008) (“An agency is not free, however, to contradict the precise requirement that Congress has already spoken to.”).

² *Aristocrat Techs. Australia Pty Ltd. v. Int’l Game Tech.*, 491 F. Supp. 2d 916 (N.D. Cal. 2007), *rev’d on other grounds by Aristocrat Techs. Australia Pty Ltd. v. Int’l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008).

Second, the six-year limitations period in 28 U.S.C. § 2401(a) does not bar this action because it commenced only after Exela had a “complete and present” cause of action. Exela’s cause of action was not “complete and present” until Exela had a legally cognizable injury in 2011 and exhausted its administrative remedies in 2012. As such, this action is timely.

Third, PTO’s standing argument is equally misplaced. PTO agrees that Exela has a legally cognizable injury and falls in the “zone of interests” protected by 35 U.S.C. 371(d). PTO argues, however, that it did not cause Exela’s injury and that any injury is not redressable by this Court. Courts have consistently rejected PTO’s causation and redressability arguments. The tenuous nature of PTO’s standing argument is demonstrated by its concession of Constitutional standing in *Centigram*, a nearly identical case, and its concession of prudential standing here.

II. ARGUMENT

PTO moves to dismiss Exela’s complaint under FRCP 12(b)(1) and 12(b)(6). Under Rule 12(b)(6), a plaintiff need only plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “The purpose of a Rule 12(b)(6) motion is to test the sufficiency of a complaint” *Edwards v. City of Goldsboro*, 178 F.3d 231, 243-44 (4th Cir. 1999). Importantly, a Rule 12(b)(6) motion “‘does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.’” Accordingly, a Rule 12(b)(6) motion should only be granted if, after accepting all well-pleaded allegations in the plaintiff’s complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff’s favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief.” *Id* at 244 (internal citation omitted).

PTO argues under Rule 12(b)(1) that the complaint fails to allege facts upon which subject matter jurisdiction can be based. In assessing such facial challenges under Rule 12(b)(1), courts assume that the facts alleged in the complaint are true and “the plaintiff ... is afforded the

same procedural protection as [it] would receive under a Rule 12(b)(6) consideration.” *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982); *see also Colonial First Props., LLC v. Henrico County, Va.*, 236 F. Supp. 2d 588, 598 (E.D. Va. 2002). “[G]eneral factual allegations of injury resulting from the defendant’s conduct may suffice, for on a motion to dismiss [the court] presume[s] that general allegations embrace those specific facts that are necessary to support the claim.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992).

A. PTO’s Rejection of 35 U.S.C. § 371(d) is Reviewable

PTO argues (Br. at 22) that its rejection of the “unavoidable” standard in §371(d) is non-reviewable. To the contrary, agency action is presumptively reviewable unless clear and convincing evidence counsels otherwise.³ The essential inquiry is whether Congress intended for a particular class of plaintiffs “to be relied upon to challenge agency disregard of the law.” *Clarke v. Sec. Indus. Ass’n*, 479 U.S. 388, 399 (1987).

Here, PTO concedes (Br. at 21) that Exela falls within the “zone of interests” protected by 35 U.S.C. § 371(d), essentially admitting that Exela would be expected by Congress to challenge PTO’s rejection of § 371(d). Exela can think of no other class of plaintiffs, and PTO cites none, having an interest in challenging PTO’s rejection of § 371(d). The Supreme Court counsels in *Clarke*, however, that “[t]he inquiry into reviewability does not end with the ‘zone of interest’ test ... because at bottom the reviewability question turns on congressional intent, and all indicators helpful in discerning that intent must be weighed.” 479 U.S. at 400. “[W]e are not limited to considering the statute under which respondents sued, but may consider any provision that helps us to understand Congress’ overall purposes in the [Patent] Act.” *Id.* at 401.

³ *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967); *see also Sackett v. EPA*, 132 S. Ct. 1367, 1373-74 (2012); *Clarke*, 479 U.S. at 395 & 399.

The text and legislative history of 35 U.S.C. § 371(d) are silent on judicial review.

However, legislative history of the APA and 1952 Patent Act provide insight into Congressional thinking when these Acts were passed. In particular, legislative history of the APA shows strong Congressional preference for agency action being reviewable:

Very rarely do statutes withhold judicial review. It has never been the policy of Congress to prevent the administration of its own statutes from being judicially confined to the scope of authority granted or to the objectives specified. Its policy could not be otherwise, for in such a case statutes would in effect be blank checks drawn to the credit of some administrative officer or board. The statutes of Congress are not merely advisory when they relate to administrative agencies, any more than in other cases. **To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.**

H. R. Rep. No. 1980, 79th Cong., 2d Sess., 275 (1946) (emphasis added) (Ex. 2). Allowing judicial review by any person “adversely affected” by agency action was a fundamental purpose of the APA. Congress made this point very clear:

This section confers a right of review upon **any person adversely affected in fact by agency action or aggrieved within the meaning of any statute**. The phrase “legal wrong” means such a wrong as is specified in section 10(e). It means that something more than mere adverse personal effect must be shown in order to prevail -- that is, that the adverse effect must be an illegal effect. Almost any governmental action may adversely affect somebody -- as where rates or prices are fixed -- **but a complainant, in order to prevail, must show that the action is contrary to law in either substance or procedure. The law so made relevant is not only constitutional law but any and all applicable law.**

House Report 1980 at 276 (emphasis added) (Ex. 2). Congress intended that the APA review provisions serve as a check on unlawful agency action. *Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988) (holding that the “central purpose” of the APA is “providing a broad spectrum of judicial review of agency action”).

Shortly after passage of the APA, the then Commissioner of Patents, Casper W. Ooms, delivered a speech (Ex. 3) on how the APA would impact judicial review of PTO decisions:

Review may not be available under statutes other than the Administrative Procedure Act in interlocutory matters, matters decided by the Commissioner on petition, and in extraordinary situations, such as striking an application for fraud which has been referred to. Interlocutory matters are apparently not subject to separate review, but many of them may, as in the past, be reviewable with adjudications on the merits both in the Office and on appeal. The remedy of mandamus or equivalent review has been available in appropriate cases. **It is expected, of course, that the enactment of Section 10 will have the effect of minimizing the technical aspects of the review and its availability, and that the courts will welcome the appellant as exercising a right of review and not merely treat him as a suppliant for extraordinary remedy. Thus will the substantial purposes of the Administrative Procedure Act be served.**

Ooms, *The United States Patent Office and the Administrative Procedure Act*, 38 Trademark Reporter 149, 159 (1948) (footnote omitted, emphasis added). After passage of the APA, Commissioner Ooms believed that petition decisions were reviewable under the APA. In fact, during the Q&A section of Commissioner Ooms' testimony, he remarked specifically regarding petitions to revive that "[a] petition to revive is committed to the discretion of the Commissioner. The only review available under the Administrative Procedure Act will be by way of a proceeding in the nature of a mandamus, although it will probably no longer be called such, which will, of course, give relief only where the discretion had been abused." Ooms, 38 Trademark Rpt at 160. Importantly, Commissioner Ooms expected that courts would "welcome the appellant as exercising a right of review and not merely treat him as a suppliant for extraordinary remedy" – a far different position than PTO takes in the present case.

When the 1952 Patent Act was under consideration, the House Judiciary Committee provided the following discussion on judicial review of PTO actions:

The next chapter relates to the review of Patent Office decisions. The act of 1836 provided, for the first time, for the refusal of patents by officials known as examiners. **The legislature was jealous of the rights of the public and provided adequate means of reviewing the action of the Patent Office.** In fact, there are now two types of review. The applicant may appeal to a court of appeals especially provided, or he may file suit in the district court against the Commissioner to have his rights adjudicated by the court. This group of sections makes no fundamental change in the various appeals **and other review of Patent**

Office action, but has made a few changes in the procedure in various instances to correct some of the problems which have arisen, particularly in section 146. These details are mainly procedural.

H. R. Rep. No. 1923, 82nd Cong., 2d Sess., 7-8 (1952) (emphasis added) (Ex. 4). Congress recognized “other review” provisions for PTO action, which included the generous APA review provisions passed only a few years earlier. *Miles v. Apex Marine Corp.*, 498 U.S. 19, 32 (1990) (“We assume that Congress is aware of existing law when it passes legislation.”).

Exela’s right to judicial review is clear in view of the legislative history. “[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market.” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). “The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’” *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 146 (1989). In exercising its power under the Patent Clause, “Congress may not ... ‘authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.’” *Id.* (quoting *Graham v. John Deere Co.*, 383 U. S. 1, 6 (1966)).⁴ “The patent laws therefore seek ... to protect the public’s right to retain knowledge already in the public domain” *Pfaff v. Wells Elecs.*, 525 U.S. 55, 65 (1998).

Before passage of § 371(d), abandoned national stage patent applications could not be revived under any circumstance. However, in passing § 371(d), Congress struck a balance between the public’s right to use information already in the public domain and a foreign patent

⁴ See also *Pennock v. Dialogue*, 27 U.S. 1, 16 (1829) (“It has not been, and indeed cannot be denied, that an inventor may abandon his invention, and surrender or dedicate it to the public. This inchoate right, thus once gone, cannot afterwards be resumed at his pleasure; for, where gifts are once made to the public in this way, they become absolute.”).

applicant's right to prosecute its application, in light of mistakes that occur through no fault of its own. Congress struck that balance by allowing for revival only under the stringent "unavoidable" standard. With no authority to do so,⁵ PTO rejected § 371(d) and revived the '218 patent in manner that contradicts the statutory scheme chosen by Congress.

Nothing on the face of § 371(d) shields this statute from judicial review. Rather, legislative history of the APA and Patent Act counsel otherwise. Indeed, it is ironic that an agency who fought to be covered by the APA's judicial review provisions, *Dickinson v. Zurko*, 527 U.S. 150 (1999), now seeks just the opposite. Here, PTO argues (Br. at 21) that "USPTO's revival decision is not subject to APA review," but in its brief to the Supreme Court in *Zurko*, PTO argued and convinced the Court that "[t]he history [of the APA] demonstrates that Congress specifically considered the nature of patent proceedings and the role of the PTO, but enacted the APA without excepting the PTO from the judicial review provisions of the Act."⁶ PTO should be judicially estopped from "playing fast and loose with the courts" and "blowing hot and cold as the occasion demands." *King v. Herbert J. Thomas Mem. Hosp.*, 159 F. 3d 192, 196 (4th Cir. 1998) (applying judicial estoppel).

Even if PTO is not judicially estopped, PTO's argument (Br. at 22) that Congressional intent to preclude judicial review can be gleaned from the *ex parte* nature of revival proceedings lacks merit for at least two reasons. *First*, the revival proceeding in *Centigram Communications*

⁵ *Medtronic, Inc. v. Lohr*, 518 US 470, 512 (1996) ("Where the language of the statute is clear, resort to the agency's interpretation is improper."); *see also Rydeen v. Quigg*, 748 F. Supp. 900, 904 (D.D.C. 1990) ("Of course, the Commissioner may not exercise such discretion in a way that contradicts the purposes of the statute or is completely contrary to reason.").

⁶ Brief for Petitioner Bruce A. Lehman, Comm. of Patents at 16 & 30-31 (available at <http://www.justice.gov/osg/briefs/1998/3mer/2mer/98-0377.mer.aa.html>).

Corp. v. Lehman (i.e., revival of patent for failure to pay maintenance fees) was *ex parte*, yet this Court allowed a third-party APA action to proceed despite PTO filing a similar motion to dismiss. 862 F. Supp. 113, 117 n.9 (E.D. Va. 1994).⁷

Second, a more recent decision from this Court (Ex. 6) shows the hollowness of PTO's position in this case. In *Callaway Golf Co. v. Kappos*, No. 1:11cv266 (E.D. Va.), Acushnet filed a reexamination request with PTO in 2006 against Callaway's patents. Shortly thereafter, Callaway petitioned PTO to terminate the reexamination, arguing that Acushnet's filing was precluded by a 1996 settlement agreement. PTO denied the petition. Callaway did not appeal that petition decision. Instead, Callaway waited until conclusion of a related patent infringement and breach of contract action pending in the U.S. District Court for the District of Delaware. The Delaware court found, *inter alia*, that Acushnet breached the settlement agreement by filing the reexamination request. PTO's reexamination of the Callaway patents continued alongside the Delaware action. PTO eventually found the Callaway patents invalid. In 2011, Callaway again petitioned PTO to vacate the reexamination proceeding, this time based upon the Delaware Court's finding that Acushnet breached the 1996 agreement. PTO denied that petition.

Despite the reexamination statute providing detailed judicial review provisions for patentees, 35 U.S.C. § 315, which includes no provision for judicial review under the APA, Callaway appealed PTO's 2011 petition denial under the APA. Remarkably, PTO did not challenge the Court's jurisdiction (Mem. Op. at 12 n.5), despite an express statutory provision stating that PTO's decision to institute a reexamination is "final and non-appealable." 35 U.S.C.

⁷ PTO's attempt to distinguish *Centigram* on the basis that "*Centigram* does not even address the issue of Plaintiffs' constitutional standing" (Br. at 20-21) is disingenuous as the PTO conceded Constitutional standing in *Centigram*. See PTO Response to Centigram Motion (Ex. 5) at 25; see also *infra* at Section II.C.1.

§ 312(c). Although PTO conceded jurisdiction, Acushnet filed an amicus brief arguing that § 312(c) precluded APA review. This Court found Acushnet's argument unpersuasive:

Section 312(c) only exempts from judicial review the PTO's substantive determination that a reexamination application raises "a substantial new question of patentability." The statute does not divest the courts of jurisdiction over all decisions related to inter partes reexaminations. See, e.g., *Cooper Techs. Co.*, 2007 U.S. Dist LEXIS 88046 (reviewing whether the PTO should have granted the petition to terminate an inter partes reexamination). Similarly, Callaway's challenge does not address whether Acushnet's reexamination applications raised a substantial new question of patentability; instead, Callaway challenges the PTO's decision that it was not required to terminate the inter partes reexaminations in light of the settlement agreement or the finding in the Delaware litigation that Acushnet had breached that agreement by requesting the inter partes reexamination. Accordingly, this Court has jurisdiction to review the PTO's denial of the petition to vacate the inter partes reexaminations.

Callaway, Mem. Op. at 12-13 (Ex. 6). PTO conceded jurisdiction in the *Callaway* case, yet surprisingly contests jurisdiction here. Nonetheless, this Court's *Calloway* and *Centigram* decisions show the tenuous nature of PTO's nonreviewability argument.

If third parties like Exela are barred from seeking review of PTO's unlawful rejection of § 371(d), this conduct likely will continue and will be unreviewable by *any* party in *any* forum. This would result in unlawful continuation of abandoned patents that should remain in the public domain, thereby frustrating a core objective of the Constitution and Patent Act. In short, judicial review in this case is "necessary to ensure achievement of the [Patent] Act's most fundamental objectives." *Block v. Community Nutrition Inst.*, 467 U.S. 340, 352 (1984).

Moreover, PTO's argument has already been rejected by this Court in *Calloway* and by another district court. *Ass'n for Molecular Pathology v. USPTO* ("*Myriad*"), 669 F. Supp. 2d 365 (S.D.N.Y. 2009). PTO's cases do not counsel otherwise. Relying on the Federal Circuit's *Aristocrat* decision, PTO argues (Br. at 24) that Congress did not allow for improper revival as an infringement defense and by supposed extension of this argument, thus, Congress intended to preclude third-party challenges to PTO revival decisions under § 371(d). However, *Aristocrat*

involved the very narrow statutory question of “whether ‘improper revival’ may be raised as an invalidity defense in an action involving the infringement or validity of a patent,” and the court’s analysis turned on the specific meaning of “defense” in 35 U.S.C. § 282. 543 F.3d at 660-61.

There are key distinctions between *Aristocrat* and this case. *First*, PTO was not a party in *Aristocrat*. *Second*, Exela is not raising improper revival as an invalidity defense to a charge of infringement. As such, 35 U.S.C. § 282 is inapplicable. Rather, this is an APA action challenging PTO conduct that has already been deemed unlawful. *Aristocrat*, 491 F. Supp. 2d at 935 (“[T]he Court finds that there is undisputed clear and convincing evidence on this record to conclude that the PTO abused its discretion in failing to applying the ‘unavoidable’ standard.”).

Moreover, *Aristocrat* did not address, let alone rule on, the viability of an APA suit directly against PTO. Nor did *Aristocrat* hold, as PTO contends (Br. at 23), that PTO’s blatant rejection of § 371(d) is a mere procedural irregularity not subject to APA review. Rather, *Aristocrat* expressly limited its holding to “the circumstances of this case.” 543 F.3d at 664. A review of the parties’ briefs explains what the court meant by “circumstances of this case.” The issue before the Federal Circuit regarding the APA was whether it applied when the agency (PTO) is not a party. *Compare* Br. of Plaintiffs-Appellants *Aristocrat* at 23-34⁸ *with* Br. of Defendants-Appellees IGT at 27-30.⁹ At oral argument, the Federal Circuit questioned whether IGT was aware of any case with a cause of action brought under the APA where the agency was

⁸ Available at 2007 WL 4792763 (“IGT’s APA argument fails on the merits. The problem is fundamental: the APA provides a vehicle for suit for non-monetary relief against the government. But IGT has not properly invoked the APA by suing the government”).

⁹ Available at 2008 WL 1787655 (“*Aristocrat* complains that IGT should have ‘pleaded an APA claim’ and named the government as a defendant” but “IGT does not have an ‘APA claim’; it simply maintains that, as the courts cited above have held, the APA authorizes district courts to review the USPTO’s rulings on petitions to revive abandoned patent applications. None of those cases requires that the government be named as a defendant in subsequent patent infringement litigation.”).

not a named defendant.¹⁰ Appellant could cite no such case to the court. *Id.* Accordingly, the Federal Circuit found the APA inapplicable. The court's ruling on the APA was unremarkable and consistent with its earlier decisions. *Andrx Pharms. v. Biovail Corp.*, 276 F.3d 1368, 1380 (Fed. Cir. 2002) (holding an APA claim "can hardly lie" without the agency as a party).

A more analogous decision is *Morganroth v. Quigg*, 885 F.2d 843, 846 (Fed. Cir. 1989), where the Federal Circuit held that "the Commissioner's denial of a petition to revive a patent application is subject to review in the district court" There is no sound reason to follow *Morganroth* when PTO denies revival of a patent application and reject *Morganroth* when PTO grants revival. This is especially true in view of *Morganroth's* holding that PTO's "discretion cannot remain wholly uncontrolled" when, as here, that decision lacks "any basis in reason or common sense." *Morganroth*, 885 F.2d at 846 (quotation omitted).

None of PTO's remaining cases (Br. at 25-28) forecloses judicial review. To the extent PTO argues that these cases apply to Exela's constitutional claims, *Myriad* has considered and rejected all but one. *Myriad*, 669 F. Supp. 2d 365 (rejecting PTO's arguments based upon *Block*, *Hitachi Metals*, *Hallmark Cards* and *Syntex*). The only case not expressly rejected, *Godtfredson*, suffers the same problem. *Godtfredson* does not involve a challenge to the constitutionality of PTO's issuance of a patent or underlying policies and practices.¹¹ Rather, like the other rejected cases, the plaintiff in *Godtfredson* sought redress of alleged statutory violations. Thus, it has no applicability to Exela's constitutional claims for reasons discussed in *Myriad*.

¹⁰ Case No. 2008-1016 oral argument transcript, beginning at 39:50, available at <http://oralarguments.ca9.uscourts.gov/> (Court: "Is there any APA case that you know of, a case in which the cause of action is created by the APA, that doesn't involve the sovereign or his agent as a defendant? ... I want to know whether you've got any case, setting aside those two cases involving this precise issue, in which, as a general matter, the APA is said to grant the cause of action." Answer: "No.").

¹¹ *Godtfredson v. Banner*, 503 F. Supp. 642 (D.D.C. 1980).

Moreover, unlike § 371(d), the statutory and regulatory provisions at issue in *Syntex v. USPTO*, 882 F.2d 1570 (Fed. Cir. 1989), and *Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3 (D.D.C. 1991), placed express limits on third-party participation in the underlying PTO proceedings. And in *Syntex, Block v. Community Nutrition Inst.*, 467 U.S. 340 (1984), and *Hallmark Cards v. Lehman*, 959 F. Supp. 539 (D.D.C. 1997), the agency action at issue could be reviewed in another forum. There is no other forum for Exela's claims. *Godtfredson* is inapposite because the plaintiff in that case simply failed to exhaust its administrative remedies.

None of these circumstances is present here. In contrast to *Block*, where judicial review would have “frustrate[d] achievement of the statutory purposes,” 467 U.S. at 352, review sought by Exela furthers the purposes of the Patent Act and the Constitution by ensuring that abandoned patent monopolies remain in the public domain. In light of *Aristocrat*, unless this Court reviews PTO's rejection of § 371(d), and improper revival and issuance of the '218 patent, those decisions will be unreviewable by *any* party in *any* forum resulting in a clear wrong without a legal remedy. However, legislative history of the APA shows that it was “designed to afford a remedy for every legal wrong” H. R. Rep. No. 1980, 79th Cong., 2d Sess., 41 (1946).

PTO essentially argues that even if it completely disregards § 371(d), Congress clearly and convincingly wanted this conduct to be insulated from judicial review. None of PTO's cases supports this result. Rather, case law and legislative history counsel otherwise. *Bowen v. Mi. Acad. of Family Physicians*, 476 U.S. 667, 671-72 (1986) (“The Committee on the Judiciary of the House of Representatives agreed that Congress ordinarily intends that there be judicial review, and emphasized the clarity with which a contrary intent must be expressed ... Taking up the language in the House Committee Report, Justice Harlan reaffirmed the Court's holding in

Rusk v. Cort, 369 U. S. 367, 379-380 (1962), that ‘only upon a showing of ‘clear and convincing evidence’ of a contrary legislative intent should the courts restrict access to judicial review.’”).

* * *

In sum, cases cited by PTO provide scant, if any, support for PTO’s argument that Congress intended to preclude judicial review for PTO’s revival decisions under § 371(d). PTO’s arguments regarding Exela’s constitutional claims were expressly rejected in *Myriad*, and PTO’s arguments regarding Exela’s statutory claims were expressly rejected by this Court under similar facts in *Calloway*. More generally, however, the APA’s presumption of judicial review supports review in this case. Certainly, PTO has pointed to no clear and convincing evidence to the contrary. Rather, in view of numerous third-party challenges to PTO’s constitutional (*e.g.*, *Myriad*) and statutory (*e.g.*, *Centigram* and *Calloway*) violations, PTO has not shown that its complete disregard of § 371(d) stands as an exception to the general rule of reviewability.

B. The Present Action is Timely

Next, PTO’s statute of limitations argument also should be rejected. The parties agree that the relevant limitations period is set by 28 U.S.C. § 2401(a), which states that “every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action **first accrues.**” (emphasis added). “A limitations period ordinarily does not begin to run until the plaintiff has a ‘complete and present cause of action.’” *Bay Area Laundry & Dry Cleaning Trust Fund v. Ferbar Corp. of Cal.*, 522 U.S. 192, 195 (1997). “[A] cause of action does not become ‘complete and present’ for limitations purposes until the plaintiff can file suit and obtain relief.”¹² This is settled law for over a century.¹³

¹² *Bay Area*, 522 U.S. at 201; *see also Hair v. United States*, 350 F.3d 1253, 1260 (Fed. Cir. 2003) (“The earliest opportunity for a complete and present cause of action is that

PTO concedes that Exela has a timely cause of action challenging PTO's refusal to decide Exela's petition. Inexplicably, PTO further argues (Br. at 14) that "Plaintiffs have raised no such claim here." PTO is wrong. Paragraph 1 of the Complaint, which is incorporated into each Count, states that Exela is "seeking a reversal of the decision of the United States Patent and Trademark Office ("USPTO") **refusing to act on the petition**," and paragraph 2, which also is incorporated into each Count, states that "USPTO's **refusal to decide Exela's petition** ... was arbitrary, capricious, an abuse of discretion, not in accordance with the law, unsupported by substantial evidence, and in excess of the USPTO's" (emphasis added). Further, Exela's claim for relief requests, *inter alia*, that the Court "order[] the USPTO to **address the merits of Exela's Petition**." (emphasis added). PTO's motion is easily dismissed regarding this claim.

Regarding Exela's challenge to PTO's revival and issuance of the '218 patent and to the revival regulation (37 C.F.R. § 1.137(b)), Exela had no legally cognizable injury from PTO's actions until it was sued for patent infringement in August 2011. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F. 3d 1330, 1340 (Fed. Cir. 2007) (holding that an ANDA filer suffers the requisite injury-in-fact where its ability to secure approval of its ANDA has been prevented by an NDA holder). And, Exela had no "complete and present" claim against PTO until exhaustion of its administrative remedies in 2012. Thus, Exela's claims are timely.

moment when the plaintiff has suffered a legally recognizable harm at the hands of the defendant").

¹³ *Graham Cnty. Soil & Water Conservation Dist. v. United States ex. Rel. Wilson*, 545 U.S. 409, 418-19 (2005) ("We have repeatedly recognized that Congress legislates against the 'standard rule that the limitations period commences when the plaintiff has a complete and present cause of action.'"); *Clark v. Iowa City*, 87 U.S. 583, 589 (1875) ("All statutes of limitation begin to run when the right of action is complete").

Undaunted by controlling case law, PTO argues that the limitations period for Exela's challenge to PTO's revival and issuance of the '218 patent commenced in 2003, and for Exela's "as applied" challenge to 37 C.F.R. § 1.137(b) commenced in 2000. These arguments are factually and legally flawed. Factually, Exela did not exist until 2004. As such, Exela could not have had a "complete and present" claim against PTO in 2000 or 2003.¹⁴ Exela can find no case, and PTO cites none, supporting PTO's unique argument that a claim can accrue when the party later asserting the claim does not even exist.¹⁵ "The mere statement of the suggestion exposes its absurdity." *Elec. Power Supply Ass'n v. FERC*, 391 F.3d 1255, 1264 (D.C. Cir. 2004).

Legally, PTO's reasoning is flawed because it presumes that mere revival of the '218 patent and mere issuance of 37 C.F.R. § 1.137(b) was "final agency action," allowing Exela to bring a civil action when these events occurred. PTO, however, completely ignores the need for an injury-in-fact before bringing a civil action in federal court. *P&V Enters. v. U.S. Army Corps of Eng'rs*, 466 F. Supp. 2d 134, 143 (D.D.C. 2006) (holding that standing to bring an "as-applied" challenge requires that the plaintiff be "personally 'injured by agency action'"). Indeed, over a decade ago, the Supreme Court in *Lujan v. National Wildlife Federation* held that:

Under the terms of the APA, respondent must direct its attack against some particular "agency action" **that causes it harm**. Some statutes permit broad

¹⁴ See *Johnson v. United States*, 544 U.S. 295, 305 (2005) (calling it "highly doubtful" that Congress intended a time limit on pursuing a claim to expire before the claim arose); *Reiter v. Cooper*, 507 U.S. 258, 267 (1993) ("While it is theoretically possible for a statute to create a cause of action that accrues at one time for the purpose of calculating when the statute of limitations begins to run, but at another time for the purpose of bringing suit, **we will not infer such an odd result in the absence of any such indication in the statute.**") (emphasis added); *Ladd v. United States*, 630 F.3d 1015, 1024 (Fed. Cir. 2010) (quoting same).

¹⁵ See *TRW Inc. v. Andrews*, 534 U.S. 19, 34 n.6 (2001) ("The question presented in *Bay Area Laundry* was whether a statute of limitations could commence to run on one day while the right to sue ripened on a later day. We answered that question ... 'no,' unless the statute indicates otherwise.").

regulations to serve as the “agency action,” and thus to be the object of judicial review directly, even before the concrete effects normally required for APA review are felt. Absent such a provision, however, **a regulation is not ordinarily considered the type of agency action “ripe” for judicial review under the APA until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant’s situation in a fashion that harms or threatens to harm him.**

497 U.S. at 891 (emphasis added). Exela suffered no harm (and no threat of harm) when PTO issued the challenged regulation in 2000, or when PTO revived the ‘218 patent in 2003. Exela did not exist on these dates. Rather, Exela initially felt adverse effects from PTO’s wrongful conduct when Exela was sued for infringement in August 2011. Once Exela exhausted its administrative remedies in 2012, its claim became “complete and present.” PTO never cites, let alone distinguishes, controlling Supreme Court precedent rejecting its limitations defense.

PTO concedes that § 2401(a) does not apply to Exela’s “as-applied” challenge to § 1.137(b). PTO argues (Br. at 14), however, that this challenge must be dismissed because that regulation was not applied directly to Exela. This argument lacks merit. The APA provides a remedy to any person “adversely affected or aggrieved by agency action.” With competitive injury as here, the challenged regulation typically is applied in favor of a third-party competitor (here SCR Pharmatop) in a manner that “adversely affects” a competitor not before the agency (here Exela). These are typical facts for competitor standing. No competitor, however, could ever challenge agency regulations under PTO’s logic and reasoning, which crumbles under the weight of numerous competitor standing decisions such as *Association of Data Processing Service Organizations, Inc. v. Camp*, 397 U.S. 150 (1970). In *Data Processing*, the regulation was never applied directly against the Plaintiff, yet the Court reviewed the action under the APA.

Still undaunted by controlling case law, PTO cites a Ninth Circuit decision, *Wind River Mining Corp. v. United States*, 946 F.2d 710 (9th Cir. 1991), as “authority” for its argument

(Br. at 13-14) that an “as-applied” challenge can only be brought when directly applied against the plaintiff. *Wind River* does not support PTO. In *Wind River*, the Bureau of Land Management (BLM) issued a decision in 1979 establishing 138 Wilderness Study Areas (WSA), which precluded companies from performing certain mining activities on these properties. When that decision issued in 1979, Wind River Mining Corporation (“Wind River”) had no interest in any of the designated properties. However, between 1982 and 1985, Wind River staked mining claims on certain properties affected by the 1979 decision. At that point, Wind River felt the effects of the 1979 decision. Then, in 1986 and 1987, Wind River petitioned the agency to change its original 1979 decision. The agency refused that petition in 1987. Wind River filed suit in 1989 – ten years after the original 1979 decision. On appeal, the Ninth Circuit held that Wind River’s suit was not barred by § 2401(a). Contrary to PTO’s position in this case, the Ninth Circuit did not find that the limitations period started in 1979. Instead, the court ruled that the limitations period started in 1987 when BLM finally rejected Wind River’s petition. Of importance, Wind River had no interest in the property when BLM issued its 1979 decision. Rather, the claim became “complete and present” only after Wind River acquired an interest in the property and exhausted its administrative remedies. *Wind River*, 946 F.2d at 715.

Analogizing *Wind River* to this case, the limitations period in § 2401(a) did not begin in 2000 when PTO issued §1.137(b) or in 2003 when PTO revived the ‘218 patent. Instead, it started in 2012 when PTO rejected Exela’s petition. Further, Exela had no reason to discover that the ‘218 patent was revived beyond PTO’s authority until near the time Exela was sued for infringement. Before issuance of the ‘218 patent, neither Exela, nor any member of the public, could have suffered any particularized injury from the PTO’s improper revival of the ‘218 patent. *Wind River* supports Exela, not PTO. Subsequent cases follow *Wind River*.

For example, in *North County Community Alliance, Inc. v. Salazar*, 573 F. 3d 738 (9th Cir. 2009), the Ninth Circuit held that a 2007 challenge to a 1993 agency decision was timely under § 2401(a), based upon the holding of *Wind River*. In 1993, the National Indian Gaming Commission (NIGC) approved a petition by the Nooksack Indians to engage in gaming operations. In 2006, the Nooksack Indians began constructing a Casino on certain property located near the plaintiff. In 2007, the plaintiff, Alliance, filed suit, alleging that NIGC violated the relevant statute by failing in 1993 to determine whether the land on which the Casino was built was Indian land. Like PTO, the agency moved to dismiss the claim, arguing that it was time-barred by § 2401(a). The Ninth Circuit rejected the motion, holding that the limitations period could not have commenced until Plaintiffs were actually affected by the 1993 decision. *North County*, 573 F. 3d at 743.

Similarly, had it even existed in 2000 or 2003, Exela would have had no idea it would be affected by PTO's rejection of § 371(d) and revival of the '218 patent. Notably, the agency's decision in *North County* was never "applied directly" to the plaintiffs in that case. This undercuts PTO's argument that the challenged regulation must be applied directly to Exela. Simply put, neither *Wind River* nor its progeny supports PTO's argument.

* * *

In sum, PTO's statute of limitations defense based upon § 2401(a) must be rejected as being factual and legally erroneous. Factually, Exela did not exist on the dates PTO alleges Exela's claims accrued. And legally, well-established Supreme Court case law holds that no claim "accrues" until Exela had a "complete and present" claim. This did not occur until 2012. Moreover, there is no requirement that the challenged regulation be applied directly against

Exela as argued by PTO. The case cited by PTO simply does not support its argument. Rather, it supports Exela. PTO's statute of limitations defense, thus, must be rejected.

C. Exela Meets Article III Standing Requirements

Finally, PTO's standing argument also should be rejected. To satisfy Article III standing requirements, Exela need only allege (1) an actual or imminent injury, that (2) is fairly traceable to the defendant's conduct, and (3) is likely to be redressed by judicial relief. *Lujan*, 504 U.S. at 560-61; *Caraco Pharm. Labs., Ltd. v. Forest Labs.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008). A plaintiff also must fall within the "zone of interests" protected by the statute. *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388 (1987). Exela satisfies each element, as explained below.

Before turning to the elements individually, however, the error of PTO's argument easily can be seen by comparing this case to *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008). In *Caraco*, Caraco Pharmaceutical Laboratories planned to manufacture a generic version of a drug called Lexapro®. Forest Laboratories, however, listed its '712 and '941 patents in the FDA's Orange Book. Caraco sued Forest, seeking a declaratory judgment that Caraco's manufacture of the generic drug would not infringe the '941 patent. Forest argued that Caraco lacked standing. The Federal Circuit disagreed, finding the requirements of injury, traceability, and redressability all satisfied.

First, the Federal Circuit found an injury because "Caraco allege[d] it [was] being excluded from selling a non-infringing product because Forest has taken actions that delay the FDA from approving Caraco's ANDA." *Id.* at 1291. The court explained: "If Caraco is correct that its generic drug does not infringe Forest's '941 patent, then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions is a sufficient Article III injury-in-fact." *Id.* at 1292. Similarly, as explained in more depth below, if Exela is

correct that PTO improperly issued the '218 patent, then the '218 patent's exclusion of Exela from the generic drug market is a legally recognized injury in fact.

Second, the Federal Circuit concluded that Caraco met the traceability test and reasoned:

[I]f Forest had not listed its '712 and '941 in the FDA's Orange Book as valid patents covering the drug described in its NDA for Lexapro®, then 21 U.S.C. § 355(j)(5)(B)(iv) (2000) would not independently delay Caraco's ANDA from being approved by the FDA. Such but-for causation is sufficient to satisfy the traceability requirement of Article III standing. . . .

Here, Forest's listing of the '712 and '941 patents in the Orange-Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both those patents are invalid or not infringed by its generic drug. Under these circumstances, Forest's listing of the '941 patent (the patent-in-suit) in the Orange-Book creates an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete. It is well established that the creation of such barriers to compete satisfies the causation requirement of Article III standing.

Id. at 1292-93 (citations omitted). Again, as explained below, the same reasoning applies to Exela. PTO's improper revival and issuance of the '218 patent is "but-for" cause that creates an "independent barrier" to Exela's ability to manufacture its generic drug. But for PTO's rejection of the statute, and improper revival and issuance of the '218 patent, the barrier would not exist.

Third, the Federal Circuit held that Caraco's injury was redressable. This issue was complicated because Caraco was seeking a declaratory judgment only regarding the '941 patent, and not the '712, which was being litigated in another case. But the court ruled:

Caraco's injury-in-fact is redressible by a declaratory judgment that the '941 patent is not infringed. . . . If Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent, then it will only need a judgment of invalidity or noninfringement on Forest's '712 patent in order to activate [another drug]'s exclusivity period and obtain FDA approval as swiftly as possible. Thus, a favorable judgment in this action would eliminate the potential for the '941 patent to exclude Caraco from the drug market.

Id. at 1293. As explained below, the same reasoning applies here. Although Exela faces allegations that its drug would infringe both patents, obtaining a favorable ruling in this case that

the '218 patent was improperly revived and issued would eliminate the potential for the '218 patent to exclude Exela from the market. Although *Caraco* involves direct competitors in an infringement action, its reasoning applies equally in the standing context to this APA action.

1. PTO Does not Dispute Exela's Injury

PTO does not dispute (Br. at 21) that Exela has a legally cognizable injury and is within the “zone of interests” protected by § 371(d). The PTO has also conceded Constitutional standing in another case involving nearly identical facts. Specifically, PTO conceded in *Centigram* that the assertion of a revived patent in a separate infringement lawsuit is a “threat of injury” that confers Constitutional standing under Article III:

Since plaintiff is being sued for patent infringement in the above-identified California case and 37 C.F.R. § 1.378(c) (1993) was used by the Commissioner to reinstate the two VMX patents subsequent to their expiration (E000314, E000315), a threat of injury to plaintiff (i.e., the case or controversy constitutional requirement for standing) based on the Commissioner's use of the rule is not contested. However, under Supreme Court precedent, plaintiff must also meet the prudential requirement for standing in order to seek to invalidate the above-noted PTO rule.

PTO Response to Centigram Motion (Ex. 5) at 25 (emphasis added).¹⁶ Given that PTO conceded constitutional standing in *Centigram* and concedes prudential standing in this case (Br. at 21), its argument that Exela lacks standing is illogical and should be rejected.

Moreover, PTO severely understates and oversimplifies Exela's injury. Exela's injury from PTO's improper revival and issuance of the '218 patent is not just the pending patent infringement lawsuit. Rather, as held in *Caraco*, Exela's injury from the '218 patent includes “an independent barrier to the drug market that deprives [Exela] of an economic opportunity to

¹⁶ Given this concession, PTO's attempt to argue (Br. at 20-21) that “*Centigram* does not even address the issue of Plaintiffs' *constitutional* standing” is disingenuous.

compete.” *Caraco*, 527 F.3d at 1293. Independent of the ‘222 patent, the ‘218 patent excludes Exela from competing today in the marketplace.

It is well settled that economic harms, such as “when the government acts in a way that increases competition or aids the plaintiff’s competitors,” suffices as a legally cognizable injury-in-fact. *Canadian Lumber Trade Alliance v. United States*, 517 F.3d 1319, 1332 (Fed. Cir. 2008). Here, PTO’s wrongful conduct has aided Exela’s competitor, SCR Pharmatop, by granting it a patent that it was not entitled to receive. Exela feels this harm today. Designing around this patent has caused Exela past, present and continuing economic harm.¹⁷ This patent also has been asserted against Exela in a separate pending lawsuit in Delaware, which is at the very least a larger and more expensive lawsuit than Exela would have had to defend had PTO not revived and issued the ‘218 patent.¹⁸ Similarly, assertion of the ‘218 patent against Exela has precluded the Food & Drug Administration (FDA) from approving Exela’s generic version of Ofirmev for at least 30-months from filing of the Delaware lawsuit. The Federal Circuit in *Caraco*, as described above, held that “[t]his is exactly the type of injury-in-fact that is sufficient to establish Article III standing under our caselaw.” *Caraco*, 527 F. 3d at 1292.

Because it is clear that Exela has suffered legally cognizable injuries and is within the zone of protected interests, the only standing questions raised in PTO’s motion are (1) whether Exela’s injury is redressable by a favorable decision of this Court, and (2) whether Exela’s injury

¹⁷ For example, Exela invested thousands of dollars researching and developing a product and manufacturing process that avoids infringement of the ‘218 and ‘222 patents. Certain steps of that process exist only because of the ‘218 patent.

¹⁸ The increased costs from the ‘218 patent, which are real and continuing, are legally-cognizable injuries-in-fact. *Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010) (“Because the Guidelines have intensified the competition for a share in a fixed amount of money, the **plaintiffs will have to invest more time and resources to craft a successful grant application. That is an actual, here-and-now injury.**” (emphasis added)).

is “fairly traceable” to PTO’s revival and issuance of the ‘218 patent. As explained below, both questions are easily answered in Exela’s favor.

2. Exela’s Injury is Redressable by this Court

PTO asserts (Br. at 17) that the redressability requirement prevents Plaintiffs from challenging the ‘218 patent in this case because “unless the ‘222 patent—the validity of which Plaintiffs do not challenge here—were also invalidated, this Court cannot presently redress Plaintiffs’ injury.” In other words, PTO argues that because this Court cannot redress any alleged “injury” from the ‘222 patent, which is not at issue here, this Court cannot redress any injury from the ‘218 patent. Similar arguments have been rejected on numerous occasions by the Supreme Court. *See, e.g., Larson v. Valente*, 456 U.S. 228, 243, n.15 (1982) (“[A] plaintiff satisfies the redressability requirement when he shows that a favorable decision will relieve a discrete injury to himself. He need not show that a favorable decision will relieve his every injury.”); *see also Massachusetts v. EPA*, 549 U.S. 497, 525 (2007) (same, quoting *Larson*). The Supreme Court’s clear rejection of this argument explains the absence of legal support in PTO’s brief. Nonetheless, this argument falls under the weight of Supreme Court case law.

For example, in the Supreme Court’s landmark ruling in *Village of Arlington Heights v. Metropolitan Housing Development Corp.*, 429 U.S. 252 (1977), a real estate developer (MHDC) sought to build a housing development. *See* 429 U.S. at 256-257. Local authorities, however, refused to rezone the property to allow the construction. *See id.* at 258. In addressing the redressability test, the Supreme Court notably held that it is not necessary to remove all potential obstacles to a project in a single lawsuit in order to establish standing. The Court ruled:

Here there can be little doubt that MHDC meets the constitutional standing requirements. The challenged action . . . stands as an absolute barrier to constructing the housing MHDC had contracted to place on the . . . site. If MHDC secures the injunctive relief it seeks, that barrier will be removed. An injunction would not, of course, guarantee that [the development] will be built.

MHDC would still have to secure financing, qualify for federal subsidies, and carry through with construction. But all housing developments are subject to some extent to similar uncertainties. When a project is as detailed and specific as [the one here], a court is not required to engage in undue speculation as a predicate for finding that the plaintiff has the requisite personal stake in the controversy. MHDC has shown an injury to itself that is “likely to be redressed by a favorable decision.” *Simon v. Eastern Ky. Welfare Rights Org.*, [426 U.S. 26, 38 (1974)].

429 U.S. at 261-262 (footnote omitted). The same reasoning applies here. If Exela successfully challenges the ‘218 patent here, “that barrier will be removed.” True, prevailing in this case “would not, of course, guarantee” that Exela could ultimately manufacture its generic drug. Exela would still have to overcome other obstacles, including the ‘222 patent and FDA approval. But, the “court is not required to engage in undue speculation as a predicate for finding that the plaintiff has the requisite personal stake in the controversy.” Nullifying the ‘218 patent will advance plaintiffs’ position, just as a favorable rezoning decision would redress injury to the developer in *Arlington Heights*. Again, in *Caraco*, where the plaintiff was seeking a declaratory judgment with respect to only one of two patents at issue, the court found the redressability requirement met because “a favorable judgment in this action would eliminate the potential for the [challenged] patent to exclude Caraco from the drug market.” *Caraco*, 527 F.3d at 1293.

Moreover, PTO’s redressability argument already has been heard and rejected in *Myriad v. USPTO*,¹⁹ where the court ruled as follows:

USPTO argues that Plaintiffs’ claim against it fails to meet the redressability requirement, which “examines the causal connection between the alleged injury and the judicial relief requested.” [*Allen v. Wright*, 468 U.S. 737, 753 n.9 (1984)]. The Plaintiffs ask the Court to enjoin the Defendants from taking any actions to enforce the challenged claims in Myriad’s patents. Fairly included in this prayer

¹⁹ 669 F. Supp. 2d 365, 385 (S.D.N.Y. 2009). This decision was reversed in part on other grounds by the Federal Circuit. *See* 653 F.3d 1329 (Fed. Cir. 2011). The Supreme Court subsequently vacated this decision. *See* 132 S. Ct. 1794 (2012). The Federal Circuit has now reinstated the appeal and it is currently pending. *See* 467 Fed. Appx. 890 (Fed. Cir. 2012).

for relief is a request that the Court declare unconstitutional the USPTO's policies and practices with respect to the challenged claims and similar classes of claims. Granting Plaintiffs' request for relief would serve to render the claims-at-issue definitionally invalid. As a result, the Plaintiffs would be allowed to engage in conduct currently prohibited by Myriad's patents, and the alleged injuries would be redressed.

As in *Myriad*, PTO's redressability argument should be rejected. Despite being a party in *Myriad*, PTO neither cites nor distinguishes *Myriad*. In any event, a favorable decision from this Court will eliminate at least some of Exela's injuries.²⁰ The redressability test requires no more. *Larson*, 456 U.S. at 243 n.15. Specifically, a favorable ruling will render the '218 patent without legal effect, thus removing the "aid" that PTO wrongfully bestowed upon Exela's competitor. It will terminate any further development costs Exela continues to expend relating to the '218 patent. It will remove the '218 patent from the pending district court litigation, thus reducing the scope and expense of that litigation. *Finally*, a favorable ruling will remove the '218 patent as a barrier to FDA approval of Exela's drug product. Exela's injuries clearly are redressable.

3. Exela's Injury is Fairly Traceable to PTO's Misconduct

PTO argues next (Br. at 19-21) that Exela cannot meet the traceability requirement. Again, the *Caraco* and *Myriad* decisions flatly reject this argument. In *Caraco*, the Court reasoned that the listing of a drug in the Orange Book was "but-for" cause of a generic drug

²⁰ PTO cites *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1297-98 (Fed. Cir. 2009) to support its theory that Exela's allegedly time-barred claims are not ripe. *Revolution Eyewear* is inapposite. *Revolution Eyewear* is not a standing case, and the court never addressed any standing requirements. Rather, the issue in *Revolution Eyewear* was whether a covenant-not-to-sue for past infringement divested the court of jurisdiction to hear a claim based on future infringement. The Court ultimately held that it had jurisdiction. Thus, PTO's reliance on *Revolution Eyewear* is both puzzling and misplaced. Moreover, Supreme Court precedent again flatly rejects PTO's arguments on this issue as well. Like the challenged action in *Village of Arlington Heights*, the '218 patent by itself "stands as an absolute barrier" to Exela's generic version of Ofirmev. 429 U.S. at 261-262. This is not future harm. Rather, this barrier exists today. PTO's ripeness argument, thus, must be rejected.

manufacturer's injury because it established an "independent barrier" to the manufacture of the drug. *See Caraco*, 527 F.3d at 1293. Here, PTO's improper issuance of the '218 patent is but-for cause of Exela's injury because the '218 patent stands as an independent barrier to the manufacture of Exela's generic drug.

In *Myriad*, plaintiffs, like Exela, sued PTO for issuing a patent in violation of the Constitution. PTO moved to dismiss, arguing *inter alia* that plaintiffs did not meet the traceability requirement. The *Myriad* court rejected this argument:

USPTO also argues that the Plaintiffs do not have standing because the injuries alleged are not "fairly traceable" to the USPTO's allegedly improper conduct. The "fairly traceable" requirement "examines the causal connection between the assertedly unlawful conduct and the alleged injury." *Allen*, 468 U.S. at 753 n.19. While the USPTO is correct that *Myriad's* refusal to license its patent broadly contributes to Plaintiffs' alleged injuries, the patents were issued by the USPTO, in accordance with its policies and practices. It is those policies and practices that the Plaintiffs allege are unconstitutional. The injury alleged is therefore "fairly traceable" to the USPTO.

Myriad, 669 F. Supp. at 385. As in *Myriad*, Exela challenges the legality of PTO's "policies and practices" in reviving and issuing the '218 patent. PTO argues, however, that any causal link was broken by SCR Pharmatop's "independent" decision to sue Exela for infringement. However, this argument is identical to the one rejected in *Myriad*. Here, as in *Myriad*, "the patents were issued by the USPTO, in accordance with its policies and practices." Because there, as here, PTO's "policies and practices" were directly at issue, *Myriad* rejected PTO's traceability argument. PTO offers no sound reason to divert from *Myriad's* reasoning.

Moreover, this Court, the Federal Circuit, and Supreme Court have all recognized, "but-for causation is sufficient to satisfy the traceability requirement of Article III standing." *Caraco*, 527 F.3d at 1292; *accord Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 & n.26 (1978) (stating that a "'but for' causal connection" satisfies the traceability requirement); *Glavin v. Clinton*, 19 F. Supp. 2d 543, 550 (E.D. Va. 1998) ("[A] plaintiff need

only show that the defendant's conduct complained of is a 'but for' cause of the plaintiff's alleged injury."), *aff'd*, 525 U.S. 316 (1999). Even "but for" causation may overstate what is needed to satisfy the traceability requirement. As then-Judge Alito once observed, "Article III standing demands a 'causal relationship,' but ... the Supreme Court ... has [n]ever held that but-for causation is always needed." *Khodara Envtl., Inc. v. Blakey*, 376 F.3d 187, 195 (3d Cir. 2004). In any event, PTO's actions in reviving and issuing the '218 patent are, at a bare minimum, "but for" cause of Exela's injury.

Had PTO used the "unavoidable" standard required by 35 U.S.C. § 371(d), the '218 patent never would have issued and this patent would not serve as a barrier to Exela's drug product. PTO's "but for" causal role easily satisfies Article III's traceability requirement. *Caraco*, 527 F.3d at 1292. Notwithstanding the *Myriad* decision and the "but for" causation standard, PTO nonetheless argues that Exela's injury cannot be traced to PTO. Even if that argument were not foreclosed by *Myriad*, it lacks merit.

Boiled to its essence, PTO argues that although its decision to revive the '218 patent directly enabled SCR Pharmatop to sue Exela, SCR Pharmatop's decision to bring suit occurred later and broke the chain of causation. However, as explained by the Supreme Court in *Bennett v. Spear*, such a view "wrongly equates injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation." 520 U.S. 154, 168-69 (1997); *accord Glavin*, 19 F. Supp. 2d at 550. "Where, as here, the alleged injury flows not directly from the challenged agency action, but rather from independent actions of third parties," the courts "require[] only a showing that the agency action is at least a substantial factor motivating the third parties' actions." *Tozzi v. U.S. Dep't of Health & Human Servs.*, 271 F.3d 301, 308 (D.C. Cir. 2001) (quotation omitted).

There can be no reasonable dispute that PTO's revival and issuance of the '218 patent was a "substantial factor" in Exela's injury. There could be no patent and no lawsuit without PTO's rejection of § 371(d). Beyond *Caraco* and *Myriad*, logic compels this finding. As a practical matter, the "independent" action of SCR Pharmatop in suing a competitor is not unexpected following PTO's improper revival of the '218 patent. The right to exclude, when properly granted, is a quintessential property right rooted in the Constitution. This right can only be granted by PTO. The causal connection is particularly strong in a patent matter.

PTO's argument that SCR Pharmatop's decision to bring suit broke the chain of causation also is foreclosed by *Glavin*. In *Glavin*, this Court found that various Virginia residents had standing to challenge the Census Bureau's use of statistical sampling (rather than head counts) in the decennial census. 19 F. Supp. 2d at 550. As the Court acknowledged, "States are neither constitutionally nor federally compelled to use census data in determining their congressional districts," and "[a] state's choice to use such data for this purpose constitutes an 'intervening' action that may break the chain of causation between challenged actions and alleged injury." *Id.* Nevertheless, citing *Bennett's* holding "that a defendant's action need not be the 'very last step in the chain of causation' to establish that plaintiff's injuries are fairly traceable to defendants' conduct for the purpose of satisfying Article III," this Court found standing. *Id.* The Court concluded "there is a direct correlation between decennial census population counts and federal and state funding allocations," and "implementation of statistical sampling in the 2000 census will directly result in a decrease of federal funding to the states and counties in which Plaintiffs reside." *Id.* Although plaintiffs' injury was not complete until later action by third parties, the Court found that plaintiffs had standing to challenge the Census Bureau's actions as but-for cause of its injury.

* * *

In sum, Exela has standing to challenge PTO's constitutional and statutory violations in reviving and issuing the '218 patent. Exela's injury is redressable by this Court. A favorable decision will remove the "aid" and advantage Exela's competitor received from PTO's misconduct, lessen the financial burden caused by the '218 patent, and remove the '218 patent as a barrier to Exela's drug product. Moreover, PTO's redressability argument was heard and rejected in *Myriad*. Exela's injury also is "fairly traceably" to PTO's alleged misconduct because it is at least but-for cause of Exela's injury. And like PTO's redressability argument, the traceability argument also has been heard and rejected in *Myriad*.

Finally, *Centigram* shows the tenuous nature of PTO's standing argument. In *Centigram*, PTO challenged prudential standing and conceded Constitutional standing. Having lost in *Centigram* on nearly identical facts, PTO now flip-flops and challenges Constitutional standing and concedes prudential standing. PTO's flip-flop shows the weakness in its standing argument.

III. CONCLUSION

For the reasons stated herein, PTO's motion to dismiss should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 23, 2012, I filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

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